

1 **MEDICATION GUIDE**

2 **CellCept® [SEL-sept]**
3 **(mycophenolate mofetil capsules)**
4 **(mycophenolate mofetil tablets)**

5 **CellCept® Oral Suspension**
6 **(mycophenolate mofetil for oral suspension)**

7 **CellCept® Intravenous**
8 **(mycophenolate mofetil hydrochloride for injection)**

9
10 Read the Medication Guide that comes with CellCept before you start taking it and each
11 time you refill your prescription. There may be new information. This Medication Guide
12 does not take the place of talking with your healthcare provider about your medical
13 condition or your treatment.

14 **What is the most important information I should know about CellCept?**

15 **CellCept can cause serious side effects:**

- 16 • **Possible loss of a pregnancy and higher risk of birth defects.** Women who take
17 CellCept during pregnancy have a higher risk of losing a pregnancy (miscarriage)
18 during the first 3 months (first trimester), and a higher risk that their baby will be
19 born with birth defects

20 If you are a female and are able to become pregnant

- 21 • your healthcare provider must talk with you about effective birth control
22 methods (contraceptive counseling)
23 • you should have a negative pregnancy test within 1 week before you start to
24 take CellCept
25 • you must use 2 different types of effective birth control at the same time, for 4
26 weeks before you start taking CellCept, during your entire CellCept therapy
27 and for 6 weeks after stopping CellCept, unless you choose to avoid sexual
28 intercourse completely (abstinence). CellCept decreases blood levels of the
29 hormones in birth control pills that you take by mouth. Birth control pills may
30 not work as well while you take CellCept, and you could become pregnant

31
32 If you plan to become pregnant, talk with your healthcare provider. Your
33 healthcare provider will decide if other medicines to prevent rejection may be
34 right for you. In certain situations, you and your healthcare provider may
35 decide that taking CellCept is more important to your health than the possible
36 risks to your unborn baby.

- 37 • **If you get pregnant while taking CellCept, do not stop taking CellCept. Call**
38 **your healthcare provider right away.** You and your healthcare provider should
39 report any cases of pregnancies to

40

- 41 ▪ FDA MedWatch at 1-800-FDA-1088
- 42 ▪ Genentech at 1-888-835-2555

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Talk to your healthcare provider about joining the National Transplantation Pregnancy Registry at 1-877-955-6877.

46 • **Increased risk of getting serious infections.** CellCept weakens the body’s
47 immune system and affects your ability to fight infections. Serious infections can
48 happen with CellCept and can lead to death. Types of infections can include:

49

- 50 • **Viral infections.** Certain viruses can live in your body and cause active
51 infections when your immune system is weak. Viral infections that can
52 happen with CellCept include:

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- 54 • Shingles, other herpes infections, and cytomegalovirus (CMV).
55 CMV can cause serious tissue and blood infections.
- 56 • BK virus. BK virus can affect how your kidney works and cause
57 your transplanted kidney to fail.

57

- 58 • **A brain infection called Progressive Multifocal Leukoencephalopathy**
59 **(PML).** In some patients, CellCept may cause an infection of the brain
60 that may cause death. You are at risk for this brain infection because you
61 have a weakened immune system. You should tell your healthcare
62 provider right away if you have any of the following symptoms:

63

- 64 • Weakness on one side of the body
- 65 • You do not care about things that you usually care about (apathy)
- 66 • You are confused or have problems thinking
- 67 • You can not control your muscles

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- 68 • **Fungal infections.** Yeasts and other types of fungal infections can happen
69 with CellCept and can cause serious tissue and blood infections (see
70 **“What are the possible side effects of CellCept?”**)

71

72 **Call your healthcare provider right away if you have any of the following signs and**
73 **symptoms of infection:**

74

- 75 • Temperature of 100.5°F or greater
- 76 • Cold symptoms, such as a runny nose or sore throat
- 77 • Flu symptoms, such as an upset stomach, stomach pain, vomiting or
78 diarrhea
- 79 • Earache or headache
- 80 • Pain during urination
- 81 • White patches in the mouth or throat
- 82 • Unexpected bruising or bleeding
- 83 • Cuts, scrapes or incisions that are red, warm and oozing pus

83

84 • **Increased risk of getting certain cancers.** People who take CellCept have a
85 higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell
86 your healthcare provider if you have:

- 87
- 88 • unexplained fever, prolonged tiredness, weight loss or lymph node
 - 89 swelling
 - 90 • a brown or black skin lesion with uneven borders, or one part of the lesion
 - 91 does not look like the other
 - 92 • a change in the size and color of a mole
 - 93 • a new skin lesion or bump
 - 94 • any other changes to your health
- 95

See the section “What are the possible side effects of CellCept?” for information about other serious side effects.

96 **What is CellCept?**

97 CellCept is a prescription medicine to prevent rejection (antirejection medicine) in people
98 who have received a kidney, heart or liver transplant. Rejection is when the body’s
99 immune system perceives the new organ as a “foreign” threat and attacks it.

100 CellCept is used with other medicines called cyclosporine (Sandimmune[®], Gengraf[®],
101 Neoral[®]) and corticosteroids. These medicines work together to prevent rejection to your
102 transplanted organ.

103 CellCept has been used safely and works in children who received a kidney transplant as
104 it does in adults. It is not known if CellCept is safe and works in children who receive a
105 heart or liver transplant.

106 **Who should not take CellCept?**

107 **Do not take CellCept if you are allergic to mycophenolate mofetil or any of the**
108 **ingredients in CellCept.** See the end of this Medication Guide for a complete list of
109 ingredients in CellCept.

110 **What should I tell my healthcare provider before taking CellCept?**

111 Tell your healthcare provider about all of your medical conditions, if you:

- 112 • **have any digestive problems,** such as ulcers
- 113 • **have Phenylketonuria (PKU).** CellCept oral suspension contains aspartame (a
114 source of phenylalanine)
- 115 • **have Lesch-Nyhan or Kelley-Seegmiller syndrome or another rare inherited**
116 **deficiency hypoxanthine-guanine phosphoribosyl-transferase (HGPRT).** You
117 should not take CellCept if you have one of these disorders
- 118 • **plan to receive any vaccines. People taking CellCept should not take live**
119 **vaccines.** Some vaccines may not work as well during treatment with CellCept
- 120 • **are pregnant or are planning to become pregnant.** See “What is the most
121 **important information I should know about CellCept?”**

- 122 • **are breastfeeding.** It is not known if CellCept passes into breast milk. You and
123 your healthcare provider will decide if you will take CellCept or breastfeed. You
124 should not do both without first talking with your healthcare provider
125

126 **Tell your healthcare provider about all of the medicines you are taking including**
127 **prescription and nonprescription medicines, vitamins and herbal supplements.**
128 Some medicines may affect the way CellCept works, and CellCept may affect how some
129 medicines work. Especially tell your healthcare provider if you take:

- 130 • birth control pills (oral contraceptives). See **“What is the most important**
131 **information I should know about CellCept?”**
- 132 • sevelamer (Renagel[®], Renvela[™]). These products should be taken 2 hours after
133 taking CellCept
- 134 • acyclovir (Zovirax[®]), valacyclovir (Valtrex[®]), ganciclovir (CYTOVENE[®]-IV,
135 Vitrasert[®]), valganciclovir (VALCYTE[®])
- 136 • rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®])
- 137 • antacids that contain magnesium and aluminum (CellCept and the antacid should
138 not be taken at the same time)
- 139 • sulfamethoxazole/trimethoprim (BACTRIM[™], BACTRIM DS[™])
- 140 • norfloxacin (Noroxin[®]) and metronidazole (Flagyl[®], Flagyl[®] ER, Flagyl[®] IV,
141 Metro IV, Helidac[®], Pylera[™])
- 142 • ciprofloxacin (Cipro[®], Cipro[®] XR, Ciloxan[®], Proquin[®] XR) and amoxicillin plus
143 clavulanic acid (Augmentin[®], Augmentin XR[™])
- 144 • azathioprine (Azasan[®], Imuran[®])
- 145 • cholestyramine (Questran Light[®], Questran[®], Locholest Light, Locholest,
146 Prevalite[®])

147 Know the medicines you take. Keep a list of them to show to your healthcare provider
148 and pharmacist when you get a new medicine. Do not take any new medicine without
149 talking with your healthcare provider.

150 **How should I take CellCept?**

- 151 • Take CellCept exactly as prescribed
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- 153 • Do not stop taking CellCept or change the dose unless your healthcare provider
154 tells you to
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- 156 • If you miss a dose of CellCept, or are not sure when you took your last dose, take
157 the regular amount of CellCept prescribed as soon as you remember. If it is time
158 for your next dose, skip the missed dose. Do not take 2 doses at the same time.
159 Call your healthcare provider if you are not sure what to do
160
- 161 • Take CellCept capsules, tablets and oral suspension on an empty stomach, either 1
162 hour before or 2 hours after a meal, unless your healthcare provider tells you
163 otherwise. With the approval of your healthcare provider, in stable kidney
164 transplant patients, CellCept can be taken with food if necessary

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166 • Most people take CellCept by mouth either as blue and brown capsules or
167 lavender tablets. Some people may get CellCept soon after their transplant surgery
168 as an infusion into a vein

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170 • Do not crush CellCept tablets. Do not open or crush CellCept capsules

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172 • If you are not able to swallow CellCept tablets or capsules, your healthcare
173 provider may prescribe CellCept Oral Suspension. This is a liquid form of
174 CellCept. Your pharmacist will mix the medicine before giving it to you

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176 • Do not mix CellCept Oral Suspension with any other medicine

177

178 • If you take too much CellCept, call your healthcare provider or the poison control
179 center right away

180

181 **What should I avoid while taking CellCept?**

- **Avoid pregnancy.** See “**What is the most important information I should know about CellCept?**”

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- **Limit the amount of time you spend in sunlight.** Avoid using tanning beds or sunlamps. People who take CellCept have a higher risk of getting skin cancer. (See “**What is the most important information I should know about CellCept?**”) Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer

183

184 **What are the possible side effects of CellCept?**

CellCept can cause serious side effects:

- See “**What is the most important information I should know about CellCept?**”

185

- **Low blood cell counts.** People taking high doses of CellCept each day may have a decrease in blood counts, including

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- **white blood cells, especially neutrophils.** Neutrophils fight against bacterial infections. You have a higher chance of getting an infection when your white blood cell count is low. This is most common from 3 months to 6 months after your transplant

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- **red blood cells.** Red blood cells carry oxygen to your body tissues. You have a higher chance of getting severe anemia when your red blood cell count is low

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- **platelets.** Platelets help with blood clotting

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Your healthcare provider will do blood tests before you start taking CellCept and during treatment with CellCept to check your blood cell counts.

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196 Tell your healthcare provider right away if you have any signs of infection (see
197 **“What is the most important information I should know about CellCept?”**), or
198 any unexpected bruising or bleeding. Also, tell your healthcare provider if you have
199 unusual tiredness, lack of energy, dizziness or fainting.

- **Stomach problems.** Stomach and intestinal bleeding can happen in people who take high doses of CellCept. Bleeding can be severe and you may have to be hospitalized for treatment

200

201 **Common side effects include:**

- diarrhea. Call your healthcare provider right away if you have diarrhea. Do not stop taking CellCept without first talking with your healthcare provider
- vomiting
- pain
- stomach area pain
- swelling of the lower legs, ankles and feet
- high blood pressure

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210 Side effects that happen more often in children than in adults taking CellCept include:

- stomach area pain
- fever
- infection
- pain
- blood infection (sepsis)
- diarrhea
- vomiting
- sore throat
- colds (respiratory tract infections)
- high blood pressure
- low white blood cell count
- low red blood cell count

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219 These are not all of the possible side effects of CellCept. Tell your healthcare provider
220 about any side effect that bothers you or that does not go away.

221 Call your doctor for medical advice about side effects. You may report side effects to the
222 FDA at 1-800-FDA-1088 or to Genentech at 1-888-835-2555.

223 **How should I store CellCept?**

- Store CellCept capsules and tablets at room temperature, between 59°F to 86°F (15°C to 30°C). Keep the container closed tightly
- Store the prepared CellCept Oral Suspension at room temperature, between 59°F to 86°F (15°C to 30°C), for up to 60 days. You can also store CellCept Oral Suspension in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not freeze CellCept Oral Suspension**

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- **Keep CellCept and all medicines out of the reach of children**

233

234 **General Information about CellCept**

235 Medicines are sometimes prescribed for purposes other than those listed in a Medication
236 Guide. Do not use CellCept for a condition for which it was not prescribed. Do not give
237 CellCept to other people, even if they have the same symptoms that you have. It may
238 harm them.

239 This Medication Guide summarizes the most important information about CellCept. If
240 you would like more information, talk with your doctor. You can ask your doctor or
241 pharmacist for information about CellCept that is written for healthcare professionals. For
242 more information, call 1-888-835-2555 or visit
243 www.gene.com/gene/products/information/cellcept.

244 **What are the ingredients in CellCept?**

245 **Active Ingredient:** mycophenolate mofetil

246 **Inactive Ingredients:**

247 CellCept 250 mg capsules: croscarmellose sodium, magnesium stearate, povidone (K-90)
248 and pregelatinized starch. The capsule shells contain black iron oxide, FD&C blue #2,
249 gelatin, red iron oxide, silicon dioxide, sodium lauryl sulfate, titanium dioxide, and
250 yellow iron oxide.

251 CellCept 500 mg tablets: black iron oxide, croscarmellose sodium, FD&C blue #2
252 aluminum lake, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium
253 stearate, microcrystalline cellulose, polyethylene glycol 400, povidone (K-90), red iron
254 oxide, talc, and titanium dioxide; may also contain ammonium hydroxide, ethyl alcohol,
255 methyl alcohol, n-butyl alcohol, propylene glycol, and shellac.

256 CellCept Oral Suspension: aspartame, citric acid anhydrous, colloidal silicon dioxide,
257 methylparaben, mixed fruit flavor, sodium citrate dihydrate, sorbitol, soybean lecithin,
258 and xanthan gum.

259 CellCept Intravenous: polysorbate 80, and citric acid. Sodium hydroxide may have been
260 used in the manufacture of CellCept Intravenous to adjust the pH.

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262 This Medication Guide has been approved by the US Food and Drug Administration.

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270 www.gene.com/gene/products/information/cellcept.

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